

**IN THE UNITED STATES PATENT AND TRADEMARK OFFICE
BEFORE THE BOARD OF PATENT APPEALS AND INTERFERENCES**

In re Application of:

Raghupathi KANDARAPU et al.

Art Unit: 1611

Application No.: 10/596,915

Examiner: T. M. Love

Filed: June 29, 2006

For: PHARMACEUTICAL COMPOSITION

Commissioner for Patents
P.O. Box 1450
Alexandria, Virginia 22313-1450

REPLY BRIEF

This submission is made in response to the Examiner's Answer dated May 25, 2011 for the above-identified application. The remarks below address positions set out in the Examiner's Answer.

The appealed claims remain rejected under 35 U.S.C. § 112, second paragraph. Appellants maintain that their claim language is not indefinite; the version of claim 1 in the Examiner's Answer emphasizes "a subcoating" in subparagraph (b), and "the subcoating" and "a subcoating" in subparagraph (c). "A subcoating" in (b) can be one or more coatings, and (c) requires that one or more subcoatings inhibits chemical interactions between an active ingredient and an enteric coating.

Further, the recitation in claim 1 of "an ... active ingredient" includes one or more active ingredients. It is not necessary that a subcoating inhibits chemical interactions between all active ingredients and an enteric coating, as those skilled in the art will be aware that not all pharmacologically active ingredients will exhibit such interactions. All that the claim requires is an inhibition of reactions involving one or more of the active ingredients. There is no issue of indefiniteness with the present claims.

The Examiner's Answer also misinterprets the description in claim 1 of an enteric coating. There clearly is an article present, as the claim recites "an ... enteric coating." This ground for rejection is clearly erroneous.

Thus, the rejections under 35 U.S.C. § 112 are not correct and should be reversed.

Regarding the rejection under 35 U.S.C. § 103, the Examiner's Answer mischaracterizes the applied Close et al. publication. An enteric coating is not necessarily applied to protect an active ingredient from contact with stomach acid. As described by Close et al., on page 1 at lines 6-18, an enteric coating on an aspirin core prevents irritation of the stomach lining that would be caused by contact with the drug. Nothing in Close et al. relates to the objective of the Appellants' claimed invention to avoid chemical interactions between an acidic enteric coating and an acid-sensitive drug. This is made quite clear by the teachings of Close et al. (e.g., at page 3, line 31 through page 6, line 6) to provide a core that contains a drug, such as aspirin, coat the core with a layer that contains the same or a different drug, and apply an enteric outer coating. The Close et al. approach will not meet the limitation of the presently appealed claim 1 that a subcoating inhibits interactions between a drug and an enteric coating.

Any combinations of Close et al. teachings with the teachings of Lassen will not affect patentability of the Appellants' claims. Lassen relates to a new use for the drug paroxetine, and indicates that any types of formulations, solid or liquid, can be used. The animal test example does not specify the nature of the drug formulation that was used; however, since saline was used as a comparator, one might expect that a liquid form was used. Therefore, Lassen's teachings cannot possibly cure the defects of Close et al. for establishing obviousness. No *prima facie* case for obviousness has been made out and the rejection should be reversed.

In view of the foregoing discussion, and the previously submitted Brief on Appeal, Appellants respectfully request the reversal of all of the final rejections of the appealed claims 1, 4-8, 12-18, and 21-24.

Respectfully submitted,

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